

K033100

DEC - 2 2003

TAIWAN KING STRONG CO., LTD.

No. 144, Dong Ming Road, Tachia Chen,
Taichung Hsine, Taiwan, 437, ROC
Tel: 886-4-26818417 Fax: 886-4-26812686
E-mail: kingstro@ms31.hinet.net

“ 510(k) SUMMARY ”

Submitter's Name: **TAIWAN KING STRONG CO., LTD.**

No. 144, Dong Ming Road, Tachia Chen, Taichung Hsine, Taiwan, 437, ROC
Tel: 886-4-26818417 Fax: 886-4-26812686

Date summary prepared:

September 23, 2003

Device Name:

Proprietary Name: Taiwan King Strong Powered Wheelchair TP01
Common or Usual Name: Powered Wheelchair
Classification Name: Powered Wheelchair, Class II,
21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The Taiwan King Strong Powered Wheelchair TP01 is an indoor / outdoor electric wheelchair that is battery operated. It has a base with four-wheeled with a seat and armrests. The movement of the powered wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically powered wheelchairs, wheelchairs, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

COMFORT Powered Wheelchair, Traveller LY-EB103 (K030356)

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Summary for substantial equivalence comparison:

The electronic systems between two devices are the same and all passed by the UL certificated, for instance the electronic controller, batteries and recharge. Thus the same safety level for the two devices is assured. The major differences existing of the two powered wheelchairs are the different controller, and the new device, Taiwan King Strong Powered Wheelchair TP01, is more agile and easy to storage or transportation and the predicate device, COMFORT Powered Wheelchair Traveller LY-EB103. Besides the overall dimension, the size of tires, and the weight are differences between the two devices. The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Taiwan King Strong Co., Ltd.
C/o Ke-Min Jen, Ph.D.
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K033100

Trade/Device Name: Taiwan King Strong Powered Wheelchair, TP01
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 2, 2003
Received: October 20, 2003

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

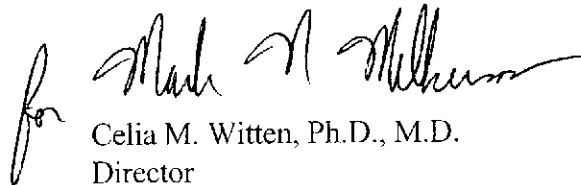
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive, flowing style.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510 (K) NUMBER (IF KNOW): TBA

DEVICE NAME: TAIWAN KING STRONG Powered Wheelchair, TP01

INDICATIONS FOR USE:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

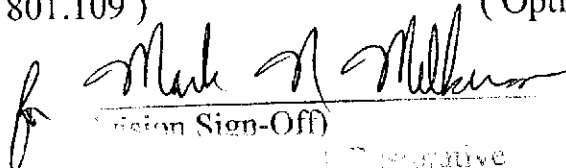
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Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ☒

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


Mark A. Miller
Deputy Director

510(k) Number K033106